K093855

JAN 15 2010

510(k) SUMMARY

BARRX Medical's [MODIFIED DEVICE]

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

BÂRRX Medical Inc.
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Date Prepared: December 20, 2009

Name of Device and Name/Address of Sponsor

HALO^{360}+ Sizing Balloon

BÂRRX Medical Inc.
540 Oakmead Pkwy
Sunnyvale, CA 94085

Common or Usual Name

Sizing Balloon

Classification Name

Product code: GEI
CFR Section: 878.4400 Electrosurgical, cutting & coagulation & accessories
Device Class: II
Classification panel: General & Plastic Surgery

Predicate Devices

HALO^{360} Sizing Balloon model 3441B (K051168)
HALO^{360}+ Ablation Catheter model 32041-XX (K083711, K071543)

Purpose of the Special 510(k) notice.

The HALO^{360+} Sizing Balloon model 3441C is a modification to HALO^{360} Sizing Balloon model 3441B and HALO^{360}+ Ablation Catheter model 32041-XX the predicate devices.

Intended Use

The HALO360+ Sizing Balloon model 3441C is intended to be used for the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus. The HALO360+ Sizing Balloon model 3441C is indicated for use for the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, and Angiodysplasia.

Technological Characteristics

The HALO360+ Sizing Balloon model 3441C is used in conjunction with either the HALO360 Energy Generator models 1100C-115B (or 1100C-230B), or HALOFLEX Energy Generator model 1190A-115A (or 1190A-230A) for assessing the size of the esophageal lumen, and facilitate the selection of the disposable single-use HALO360+ Coagulation Catheter. The HALO360+ Sizing Balloon model 3441C, like the predicate device HALO360 Sizing Balloon model 3441B is comprised of a sizing balloon, a catheter shaft with markings, and an electrical connector. The HALO360+ Sizing Balloon model 3441B is substantially equivalent in design, performance, and mode of operation with the already cleared predicate devices: HALO360 Sizing Balloon model 3441B and HALO360+ Ablation Catheter model 32041-XX.

Performance Data

The HALO360+ Sizing Balloon model 3441C met the same specifications requirements as the HALO360 Sizing Balloon and HALO360+ Ablation Catheter for the following characteristics:

- Sizing accuracy
- Structural strength
- Material compatibility
- Sterility

Substantial Equivalence

HALO360+ Sizing Balloon model 3441C has the same intended use and indications, principles of operation, and technological characteristics as HALO360 Sizing Balloon model 3441B and HALO360+ Ablation Catheter model 32041-XX. The minor differences in the HALO360+ Sizing Balloon model 3441C are:

- Changes in the balloon material
- Increase the sizing balloon capability to measure esophageal diameter higher than 33.7 mm and as result identify when the balloon migrates in the stomach.

These changes do not raise any new questions of safety or effectiveness. Performance data demonstrates that the HALO360+ Sizing Balloon is as safe and effective as HALO360 Sizing Balloon model 3441B and HALO360+ Ablation catheter model 32041-XX. Thus, the HALO360+ Sizing Balloon model 3441B is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

BARRX Medical, Inc.
% Ms. Viorica Filimon
Vice President of Quality/Regulatory Affairs
540 Oakmead Parkway
Sunnyvale, California 94085

JAN 1 5 2010

Re: K093855
Trade/Device Name: HALO^{360} + Sizing Balloon
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 15, 2009
Received: December 16, 2009

Dear Ms. Filimon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):_____

Device Name: HALO^{360} + Sizing Balloon

Indications for Use:

HALO^{360} + Sizing Balloon model 3441C is indicated for the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, and Angiodysplasia.

Prescription Use X_ (Per 21 C.F.R. 801.109) Subpart C)

AND/OR

Over-The-Counter Use____ (Per 21 C.F.R. 807

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K093855